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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/769,107	01/24/2001	Vincent P. Sandanayaka	AM-100182 PI	4495

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EXAMINER
COVINGTON, RAYMOND K

ART UNIT	PAPER NUMBER
1625	

DATE MAILED: 01/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/769,107	Applicant(s) SANDANAYAKA ET AL.	
	Examiner Raymond Covington	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 August 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-53* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-14, drawn to a method of preparing alpha-sulfonyl derivatives of formula V using a carbonyl intermediate of formula IV, classified in class 562, subclass 44, for example.

II. Claims 15-38, drawn to a method of preparing alpha-sulfonyl derivatives of formula V using a enol intermediate of formula VIII, classified in class 564, subclass 162, for example.

III. Claim 39, drawn to an alpha-sulfonyl hydroxamic compound per se, classified in class 546, subclass 216, for example.

IV. Claims 40-42, drawn to a method of preparing alpha-sulfonyl hydroxamic acids of formula IA, classified in class 546, subclass 192, for example.

V. Claim 43, drawn to a method of preparing alpha-sulfonyl carboxylic acid ester, classified in class 546, subclass 212, for example.

VI. Claim 44, drawn to a method of preparing alpha-sulfonyl hydroxamic derivative of formula 8, classified in class 546, subclass 208, for example.

VII. Claims 45-46, drawn to compounds of the formula IX, classified in class 540, subclass 470, for example.

VIII. Claim 47, drawn to a pharmaceutical composition of formula IX, classified in class 514, subclass 824, for example.

IX. Claims 48-49, drawn to a method of inhibiting TACE, classified in class 514, subclass213, for example.

X. Claims 50-53, drawn to a method of inhibiting pathological changes, classified in class 514, subclass 330, for example.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I, II, IV, V, VI, processes and III, VII, VIII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the products of groups III and VII can be made by other materially different processes

3. The inventions of I, II, IV and VI differ materially in that they employ different intermediates, produce different products and a reference anticipating one invention would not render the other inventions obvious.

4. Inventions I, II, IV, V, VI and IX, X are related as process of making and process of using the product. The use as claimed cannot be practiced with a materially different product. Since the product is not allowable, restriction is proper between said method of making and method of using. The product claim will be examined along with the elected invention (MPEP § 806.05(i)).

5. Inventions VII, VIII and IX, X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

process of using that product (MPEP § 806.05(h)). In the instant case the process for using the product as claimed can be practiced with another materially different product.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

7. Because these inventions are distinct for the reasons given above and the search required for any one Group is not required for any other Group, restriction for examination purposes as indicated is proper.

8. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Claims 1-52 are generic to a plurality of disclosed patentably distinct species comprising, for example, O-heterocyclic derivatives classified in 549/200+, S-heterocyclic derivatives classified in 549/1+, polycyclic thiomorpholine derivatives classified in 544/60+, polycyclic morpholine derivatives classified in 544/101+, diazine derivatives classified in 544/224+, thiodiazine derivatives classified in 544/8+, benzothiazine classified in 544/49+, isoquinionline derivatives classified in 546/139+, tropane derivatives classified in 546/124+, oxazole derivatives classified in 548/240+, thiodiazole derivatives classified in 548/125+, 568/38+, 568/630+, and various other species too numerous to recite. The inventions are distinct, each from the other because of the following reasons: the compounds differ materially in structure and element so much so as to be patentably distinct. In addition, a reference, which

anticipates one group, may not even render obvious the other. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. Upon election, the Examiner will review the claims and indicate (a) a generic concept inclusive of the elected species {compounds which are so similar thereto as to be part of the elected matter} and (b) by such indication (i.e. by exclusion) which compounds are drawn to non-elected subject matter.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

9. A telephone call was made to John Hogan on 11/20/02, 12/9/02,12/28/02 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claims have been searched only too the extent they read on non-heterocyclic substituted derivatives where $R_1$and R_2 from a piperidine ring.

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 39, 4645, 46 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barta et al WO 00/71514.

Barta et al teach alpha-sulfonyl derivatives as recited in the claims. See page 8, line 10 to page 13 line 22. Barta et al differ in that only the beta as opposed to the alpha derivative is disclosed. However, due to the close structural relationship of the compounds, the alpha derivative would have been obvious to one of ordinary skill in the art.

Claims 1-53 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable

one skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention.

The specification does not give any guidance as to how each of the heterocyclic substituted derivatives were prepared. In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. □ 112, first paragraph, have been described. They are:

1. The nature of the invention,
2. The state of the prior art,
3. The predictability or lack thereof in the art,
4. The amount of direction or guidance present,
5. The presence or absence of working examples,
6. The breadth of the claims,
7. The quantity of experimentation needed, and
8. The level of the skill in the art.

In the instant case, Applicants are claiming heterocyclic substituted alpha-sulfonyl derivatives. Applicants have not disclosed any working examples, which would demonstrate, or guide, one skilled in the art as to how the heterocyclic substituted derivatives other than where $R_1$and R_2 from a piperidine ring, were prepared or obtained. The process of making the heterocyclic substituted derivatives, such as for example thio-morpholine, or how the heterocyclic substituted derivatives were obtained is not readily apparent from the specification. The specification must teach how to make the invention. *In re Gardner*, 166 U.S.P.Q. 138 (1970). In order to practice the

claimed invention, one skilled in the art would have speculate how the derivatives were obtained or prepared. Therefore, the instant invention is not enabled.

Claims limiting the scope of these terms should overcome this rejection.

The status of copending application 09/492,975 should be updated in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond Covington whose telephone number is (703) 308-4704. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, A. Rotman can be reached on (703) 308-0204. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7922 for regular communications and (703_ 308-7922 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Raymond Covington
Examiner
Art Unit 1625

Covington/LR
November 6, 2002

Alan L. Rotman

ALAN L. ROTMAN
SUPERVISORY PATENT EXAMINER
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